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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,726	12/20/2001	Gerard Alaux	SANSYL001	1053

7590 01/24/2003

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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/019,726	Applicant(s) ALAUX ET AL.	
	Examiner Susan Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-14,16,19-23 and 26-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16,19-23 and 26-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Priority Document and Amendment filed 12/20/02.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 8, 9, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. US 5,425,950.

Dandiker teaches a controlled release composition comprising layer-tablet suitable for pulse release of active ingredient, including hypnotic drugs (column 2, lines 33 through column 3, lines 1-64). The layer-tablet comprises a rapidly disintegrating outer active layer, and inner layer/layers of active ingredient that will gradually remove after the rapidly disintegrating outer active layer is removed (id). The rapidly disintegrating outer active layer dissolves within 30 minutes, and the gradually inner active layer/layers dissolves from 1-3.5 hours (column 5, lines 14-23; and column 8, lines 13-53). The gradually inner active layer/layers further comprises fillers, excipient,

surfactant, lubricants, and the like (column 6, lines 65 through column 7, lines 1-2). Dandiker teaches hypnotic drug among other drugs, it is the position of the examiner that it would have been *prima facie* obvious for one of ordinary skill in this art to, by routine experimentation using hypnotic drug in the pulse release formulation, because Dandiker suggests that hypnotic drug is a suitable active ingredient in his invention (column 3, lines 59-64).

Claims 1-4, 6, 8, 9-14, 16, 19-22, 27, 28, 31-46, and 54-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha et al. US 6,340,476.

Midha teaches pulsatile delivery system comprising first, second and third dosage units having different drug release profile (see abstract). The dosage units can be in the form of tablet, coated tablet, matrix tablet, matrix particles or beads, coated particles or beads, or un-coat particles or beads to be placed in a capsule (column 4, lines 63 through column 5, lines 1-30). The delayed dosage unit can be coated or incorporated in matrix containing polymers, such as cellulose, or methacrylate polymer/copolymer (column 5, lines 23 through column 6, lines 54). The drug-containing dosage unit further comprises filler, binder, disintegrant, lubricant, and surfactant, including cationic surfactant (column 7, lines 35 through column 8, lines 1-15). The active ingredients can be selected from antidepressant drugs, analgesic, and anti-anxiety drugs, such as benzodiazepines, lorazepam, midazolam, temazepam and triazolam (column 9).

Midha does not teach the use of anti-anxiety drugs (hypnotic drug) alone in the delivery system. However, since Midha suggests anti-anxiety drugs can be used in the pulsatile delivery system, it would have been *prima facie* obvious for one of ordinary skill in this art to modify Midha's delivery system using anti-anxiety drugs with the expectation of at least similar result, because the reference teaches the advantageous results in the use of pulsatile delivery system to deliver anti-anxiety drugs, such as benzodiazepines, lorazepam, midazolam, temazepam and triazolam (column 9).

Claims 5, 7, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha et al.

Midha is relied upon for the reason stated above. Midha does not specifically teach the percent release of active agent. However, absent showing evidence on the contrary, it is the position of the examiner that the percent release of active agent is inherent, since Midha teaches pulsatile delivery system having the same release profile, *e.g.*, first dosage being released immediately upon administration, second dosage being released within 3-5 hours (column 12, lines 1-5). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation optimize the amounts of binder, disintegrant, or coating to obtain at least similar results. The expected result would be a pulsatile delivery system containing hypnotic agent useful in pharmaceutical art.

Claims 26, and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha et al., and Cuca et al. US 5,491,681.

Midha does not teach the pulsatile dosage form can be incorporated into drinkable form.

Cuca teaches active ingredients in matrix form suitable for pulsatile release can be incorporated in a drinkable form (column 7, lines 36-42). The active ingredients can be selected from antitussive, antihistamine, antitumor, hypnotics, and the like (column 3, lines 19-50). Thus, it would have been obvious for one of ordinary skill in the art to modify Midha's pulsatile delivery system with the teachings of Cuca with the expectation of at least similar result, because the references teach the advantageous results in the use of pulsatile dosage form to deliver hypnotic drugs.

Claims 23, and 68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha et al., in view of Bastin et al. US 6,309,668.

Midha is relied upon for the reasons stated above. Midha does not teach zolpidem as a hypnotic agent.

Bastin teaches multiplayer tablet formulation comprising hypnotic drugs, including zolpidem (columns 1-3). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify Midha's anti-anxiety agent (hypnotic agent) with zolpidem in view of the teachings of Bastin to obtain the claimed invention, because the references teach the advantageous results in the use of hypnotic drug in a controlled release dosage form.

Claims 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha et al., Gallopo et al. US 5,176,901.

Midha is relied upon for the reasons stated above. Midha does not specifically teach cocamidopropylbetaine as a cationic surfactant.

Gallopo teaches useful cationic surfactant including cocamidopropyl (column 4, lines 6-9). Thus, it would have been obvious for one of ordinary skill in the art to modify Midha's cationic surfactant using the cocamidopropyl in view of the teaching of Gallopo with the expectation of at least similar result, because the cocamidopropyl is a well-known and useful cationic surfactant in pharmaceutical art.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Debregeas et al., campbell et al., Conte et al., and Gold are cited as being of interest for the teachings of controlled/pulse release compositions.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600